REMARKS / ARGUMENTS

Remarks:

Applicant thanks the Examiner for his office action and for recognizing the allowable subject matter.

Claims 1 and 4 to 19 remain pending in this application. Claim 20 has been canceled. No claims have been added. No new matter has been added. Applicant maintains all rights to any subject matter reflected in the withdrawn claims, which may be claimed in subsequent application.

Arguments:

To further distinguish the invention from the cited prior art the following arguments are provided.

Concerning the cited reference US 6156006, Brosens et al., (hereinafter P1), it is noted that the specification refers to speculums merely in column 17 lines 21-50, Figs 19-21 and in column 6 lines 24-28, serving the purpose of a guide for the Veress needle of P1 invention, whereas ultrasonic probe is mentioned merely in column 14 line 57 to column 15 line 7, Fig. 9 and in column 17 line 5 to column 18 line 13, Fig. 22. The aforesaid two non-associated mentions of the two technical features present, inter alia, in the present invention, even in the context of one single publication, having no meaningful relation to each other and does not tech how to combine an ultrasonic probe of a preferable shape with vaginal speculum. The speculum in column 17 lines 21-50, Figs 19-21 and the ultrasonic probe in column 14 line 57 to column 15 line 7, Fig. 9 are used as a guide for the Veress needle of P1 invention.

Inasmuch P1 does not tech the combination of an ultrasonic probe of a preferable shape with a

vaginal speculum for IVF procedures, it neither teaches how to nor motivate1s to combine these two technical features. The aforesaid two mentions are considered to be rather sporadically apparent in the context of P1 and do not provide one skilled in the art neither guidance nor inspiration to combine these two technical features.

Concerning particularly US 3320948, Martin, (hereinafter P2), firstly no ultrasonic probe mentioned at all and no mention of "inspection device" couldn't have found either. The mounting mechanism, although associated with the handle 35, which inter alia supports the lower jaw of the speculum in P2, is actually positioned on an hinge formed in-between apertures 41, substantially in the centre of the opening formed the bases of the two jaws. Such configuration is completely inappropriate for the aim and do not provide for the clinical benefit achieved by the present invention, namely a tool useful in Assisted Reproductive Technologies (ART) procedures, in general, and an embryo transfer during In-Vitro Fertilization (IVF) procedure or an Intra Uterine Insemination (IUI) procedure, in particular. Furthermore the mounting mechanism 4 in P2 substantially differs from the equivalent of the mounting mechanism in the present invention. The mounting mechanism in the present invention associated with one of the jaws, preferably the upper one, whereas the equivalent of the mounting mechanism in P2 is associated with handle 35 and installed therein by being pivoted between end sockets 36. The aforementioned positioning of the mounting mechanism in P2 substantially obstructs the field of view and the operative access of the physician performing IVF and/or IUI; what makes the speculum of P2 with the mounting mechanism thereof unsuitable for the clinical purposes accomplished by the present invention. Moreover, the fact the mounting mechanism in P2 is installed being pivoted between end sockets 36 once again emphasizes the different technological problem underlying P2 and the present invention; since if on operative tool, such as forceps, to be mounted on the mechanism of P2 is substituted with an ultrasonic probe, the clinical benefit of the present invention will not be achieved. In this respect, the distinction between an ultrasonic probe and an operative tool is pivotal, since it is preferable for an ultrasonic probe to not interfere with an operational procedure and to neither obstruct the field of view nor the operative access to the desired site.

In respect to claim 13, the limitation "adapted to be inserted" was replaced with "inserted" to

impose a positive limitation in a patentable sense (In re Hutchison, 69 USPQ 138).

Concerning particularly P1 taken in view of US 6371973, Tepper, (hereinafter P3), the Examiner asserts that:

> *Brosens et al. disclose all elements of the claimed invention except for the specific details of the mounting mechanism or mounting configuration. Tepper teaches an instrument mount including: a housing 32; first clamping element 34; a second clamping element or locking mechanism 35 that when engaged or locked to second clamping element 35 prevents movement of an instrument such as an ultrasound probe with respect to the instrument that it is attached to; and a fastener or pins 44 that secure the first clamping element to housing 32 (Fig. 3, col. 7, lines 26-67 and col. 8, lines 1-17).*

It is firstly noted that not all the features, namely degrees of freedom in positioning of the ultrasonic probe, are available at the instrument mount of P3. The instrument mount of P3 does allow an axial translation of the ultrasonic probe, however the aforementioned mount do not provide for a rotational translation of the same. Hence P3 neither discloses all elements of the claimed invention nor the specific details of the mounting mechanism or mounting configuration.

The Examiner further asserts that:

> *The substitution of one known instrument mounting mechanism (as taught by Tepper) for another known instrument mounting mechanism (as disclosed by Brosens et al.) would have been obvious to one of ordinary skill in the art at the time of the invention since this amounts to simple substitution of one known type of mounting mechanism for another and would have yielded*

predictable results, namely, removable attachment of an ultrasound probe to an instrument, for e.g. a speculum.

It is further noted that even if, hypothetically, the mounting mechanism of P3 was capable of the complete functionality of the mounting mechanism of the present invention, e.g. to perform with all the degrees of freedom in positioning of the ultrasonic probe, the combination of the features of P1with P3 would not have been obvious to one of ordinary skill in the art; since there is no teaching or suggestion for such a combination or substitution, in neither of the prior art publications cited by the Examiner. Accordingly, the combination of P1 with P3 can only be made by the exercise of hindsight, taken in the light of the present invention.
In respect to claim 13, the limitation "adapted to be inserted" was replaced with "inserted" to impose a positive limitation in a patentable sense (In re Hutchison, 69 USPQ 138).

Concerning in particular the rejection of claim 20 based on P2 taken in view of US 6371973, Wong, (hereinafter P4), claim 20 was canceled without prejudice.

External Evidences:

Applicants ask to present the Examiner external evidences asserting the inventive value of the pending claims. The present invention was conceived and reduced to practice by Prof. Adrian Shulman, a key opinion leader in the field of gynecology in Israel and abroad, Dr. Michal Devir, one of the primary gynecologist physicians in Israel, and Mr. Gershon Goldenberg a preeminent developer of innovative IVF technologies. The team has aimed at improving the relatively low success rate at IVF and IUI procedures. After having analyzed the factors having the most profound effect on the success rate at IVF and IUI procedures, the team has come to the conclusion that the inefficient and prolonged procedure of an embryo transfer and insemination dramatically affects the success rate at IVF and IUI procedures respectively. The team has further articulated the technological solutions for the objective problem underlying the present invention and engaged in the development of a device that implements these solutions; thereby efficiently reducing the time period required for the procedures of embryo transfer

during IVF and artificial insemination during IUI.

A prototype was then created and the team approached the Helsinki committee of the Ha Emek Hospital, Afula, Israel, to obtain a permit for the clinical trials of the device. A permit for a feasibility/safety trial was obtained; please refer to Annex 1 for the copy of the permit (the permit of Annex 1 is a Hebrew written document, upon request a legal translation of the permit shall be provided). Protocols for the trail and guidelines for the participants were articulated as well; no copies of such protocols and guidelines are annexed hereto since they are also Hebrew written documents (upon request a legal translation of these documents will be provided).

The aforementioned feasibility/safety trial was then conducted and the outcomes thereof were very promising. At this point, it was decided to present the prototype of the invention and the results of the trails to the professional community of gynecology physicians. The prototype of the invention was then exhibited at the annual ESHRE (European Society of Human Reproduction and Embryology) conference, of June 2007 at Prague, Czech Republic. Please refer to Annex 2 for examples of photographs and presentational materials, e.g. posters, postcards, etc., of the ESHRE exhibition. Emphasis added to the substantial similarity/identity between the prototype as presented at the ESHRE exhibition and the device of the present invention, as apparent in the appended drawings. The attendants of the ESHRE conference were also presented with the outcomes of the aforementioned feasibility/safety trial.

Examiner's attention is drawn to the fact that the professional community of gynecology physicians, attendants of the ESHRE conference, has exhibited a profound excitement and vast enthusiasm in relation to the presented subject matter. Since the presentation at the ESHRE exhibition and up until now there are virtually innumerous replies, feedbacks, requests, pleas and concrete propositions to acquire the device, from gynecologists across Europe and elsewhere. The correspondences of three arbitrarily selected propositions are presented in Annex 3. It is stressed that there are numerous other requests, exemplified by Annex 3, which will be provided upon request. In light of the foregoing, applicants assert that neither of P1 to P4, nor other prior art made of record for that matter, do not possess the clinical benefit

achieved by the present invention. Applicants ask the Examiner to acknowledge that such a profound effect generated by the professional community of European gynecologist affirmatively demonstrates the inventive value of the present invention. Applicants further ask, in the event of this arguments are considered as non-persuasive, to hold a telephonic interview Examiner in order to elucidate the professional gynecology-related constrains associated with the prior art devices/methods and how do they are overcome by the present invention.

Summary:

In light of the above-listed amendments and accompanying arguments, applicants believe that the rejections presented by the Examiner in the office action mailed to applicants on 03/17/2009 were overcome. Applicants therefore hope that the Examiner will allow the application with the claims as amended to proceed to acceptance. Reconsideration and withdrawal of the rejection and issue of a notice of allowance on the pending claims is respectfully solicited.

Respectfully submitted,

/Prof. Adrian Shulman/

Prof. Adrian Shulman

/Dr. Michal Devir/

Dr. Michal Devir

/Mr. Gershon Goldenberg/

Mr. Gershon Goldenberg

Attachments: Annexes 1 to 3

Annex 1

מדינת ישראל
STATE OF ISRAEL

משרד הבריאות
הרשות לטכנולוגיות רפואיות ותשתיות
מינהלת למכשירים ומבשירים רפואיים

Ministry of Health
Health Technology and Infrastructure Administration
Medical Devices Department

אישור מנהל משרד הבריאות
לפי תקנות בריאות-העם (נכרים רפואיים בבני-אדם) התשמ"א 1980

תאריך: 14.9.05

לכבוד
פרופ' חנה מבנקין
יו"ר ועדת אלסינקי
בית חולים העמק
עפולה 18101

נכבדי,

הנדון: **אישור לשימוש בכרי בדיקה בבני אדם**
מסמכים: אישור ועדת הלסינקי מיום:

הבקשה מאושרת.	מס' האישור:	HTA3095
מס' הבקשה:		HT3095
שם חוקר ראשי:		ד"ר ויים אמיר .
שם הנכרי:		**סטרילום ואיניטי GRAVE בצרוף US.**
שם היצרן:		**יוסט מדיקל בע"מ USED MEDICAL LTD.**
שם הנציגי הרשאי:		שימוש חדשה לביצוע החזרת עוברים בהפריה חוץ גופית והזרעה תוך רחמית תחת הדמיית אולטרה-סאונד מבוקנת, מס' 3840505
מסמכי העיסוי:		פרוטוקול מ- 26.6.05; טופס הצהרה שהתקבל ב- 07/07/2005; נספח 1 מ- 26.6.2005; חוברת למוקר מ- 26.6.05; מכתבו של היוזם, ד"ר דידי פרנק, מ- 12.7.05;

תנאים מצטברים:
1. תוקף האישור: 15.9.2006

הערות כלליות: במסגרת של התקשרות מסחרית לביצוע הניסוי הרפואי בין היוזם, החוקר הראשי והמוסד הרפואי, רשאי מנהל המוסד הרפואי לדעתיק אישור לניסוי לאחר שקבע כי תחת ההתקשרות עומד בכל דרישות הנוהל לניסויים רפואיים בבני אדם של משרד הבריאות (1999).

בכבוד רב,
אסתר בן
רכזת ארצית לניסויים קליניים באמ"ר
ב/מנהלת אגף הרוקחות

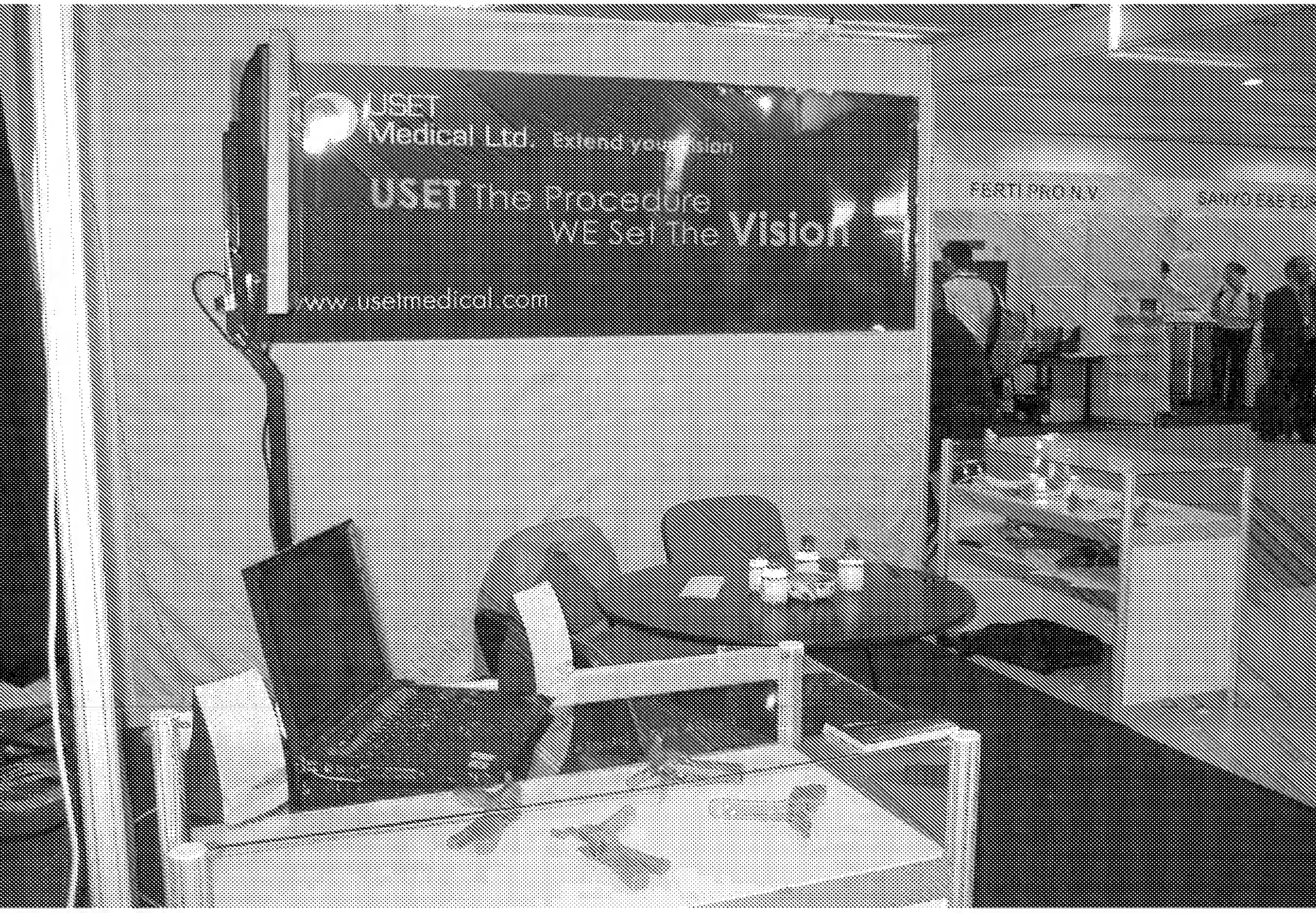
העתק: ד"ר אורנה פלונסקיים, מנהל בית החולים העמק.
ד"ר הלפרין, ראש מחלקת בית החולים בשירותי בריאות כללית.
מר' בתיה הרן, מנהלת אגף הרוקחות
אינג' נדב שפר, מנהל יחידת האמ"ר

23 Ha'Arba'a Str. P.O.Box 1176, Jerusalem 91010
ISRAEL
Tel: 972-2-5403333; פקס: 972-2-5403337
מחלקת מכשירים קליניים: 02-5403218/330

Tel Aviv Branch:
Sheba Medical Center, Bldg 138,
Tel Hashomer 52621
טל: 972-3-5303291/3; פקס: 972-3-5344812

Haifa Branch
Regional Health Services Center
13 A. Pal-Yam Blvd.
Haifa P.O.B.8000, Haifa 31080
טל: 04-8633666
פקס: 04-8633667

Annex 2


USET
Medical Ltd.
USET the Procedure
We Set the Vision
www.useimedical.com

USET enables you to perform intrauterine procedures during real-time transvaginal ultrasound.

Visit us at:

www.usetmedical.com

About Us

USET Medical Ltd. was founded in 2004 at the Yozmot Business Incubator in Israel. The company has developed a unique method of real-time sonography guidance for intra-uterine procedures. USET's devices enable the physician to perform embryo transfer and other intrauterine procedures during real- time transvaginal ultrasound.
The device is a vaginal speculum assembly that allows for the mounting of an ultrasound probe on one of the blades. This allows for the high-resolution real-time ultrasound visualization of the targeted organ. As a result, surgeons are able to perform the procedure safely and efficiently. Because this technology is safe, simple and low-cost, **USET Medical** is confident that the use of real-time transvaginal ultrasound guidance -- and its device - will eventually become a standard way of performing intrauterine procedures.

Growing incidence of intra-uterine procedures

The advances in technology allow millions of women worldwide to protect themselves each year by undergoing some form of intra-uterine intervention. They may seek help as part of infertility treatment, for tests during pregnancy or for the insertion/removal of contraceptives device.

Such procedures include:

- Embryo transfer during in-vitro fertilization (IVF).
- Chorionic Villi Sampling (CVS)
- Hydrosonography
- Intra-Uterine Insemination (IUI)
- Insertion or removal of an Intra-Uterine contraceptive Device (IUD)

USET the Procedure, WE set the Vision

The Use of ultrasound monitoring during intra-uterine procedures

Since the birth of the first in-vitro fertilization (IVF) baby in 1978, there have been phenomenal advances in ovulation stimulation regimes, oocyte collection and culture mediums.

Similarly, medicine has seen vast improvements in ovulation induction, fertilization and embryo cleavage. However the technique of transferring uterine embryos has remained largely unchanged since its inception, with most transferred embryos failing to implant. This failure may be attributed to deficiencies in either intrinsic embryo quality or uterine receptivity as suggested by Speirs (1988). It may also be due to the transfer technique itself.

In most fertility centers, surgeons who perform embryo transfer and other intrauterine interventions rely on the sense of touch in order to position the transfer catheter in the upper part of the uterine cavity, and the procedure is performed without online vaginal ultrasound monitoring. Being able to use vaginal ultrasound can greatly assist catheter positioning. It can help to accurately guide the catheter to the optimal place for effective embryo delivery in IVF procedures.
It is widely accepted today that ultrasonic guidance enhances embryo transfer. The procedure should be performed during real time trans vaginal ultrasound monitoring to ensure correct positioning of the embryo transfer catheter.

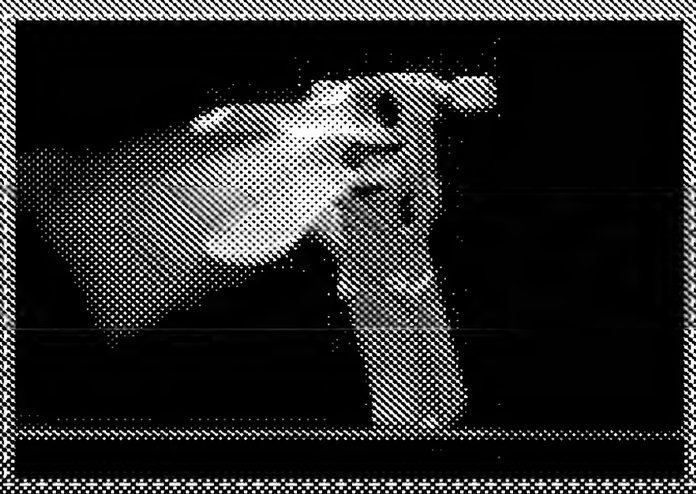
USET's Device

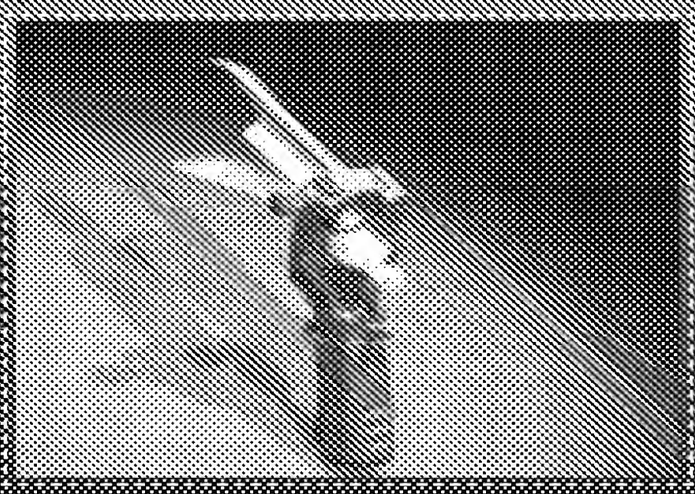
From its first use, the new speculum from USET Medical shows its inherent advantages for intra-uterine surgical procedures, while it enables the physician to perform intrauterine procedures during real-time transvaginal ultrasound monitoring.

- **Visible Intrauterine Procedures** – In preference to the traditional 'blind' method, adding ultrasound allows the visualization of the uterine cavity and thereby increases the effectiveness of these procedures.
- **Greater ART success** – Increased success rates of ART treatments, eliminating the need for repeated expensive and complicated treatments.
- **Enhanced confidence** – Using an ultrasound image as a guidance factor contributes greatly to the physician's confidence and to patient safety.
- **Minimum complications** – The risk of complications is reduced to a minimum, resulting in lower overall costs of surgical treatment.
- **Ease of application** – Any gynecologist with a basic expertise in ultrasound can use the USET speculum in ambulatory conditions. It is simple to use and does not differ in application from a conventional speculum.
- **Versatility** – The new device is equipped with a set of versatile adapters and blades that allow a wide range of ultrasound transducers. It is suitable for women before the first pregnancy as well as after several deliveries.

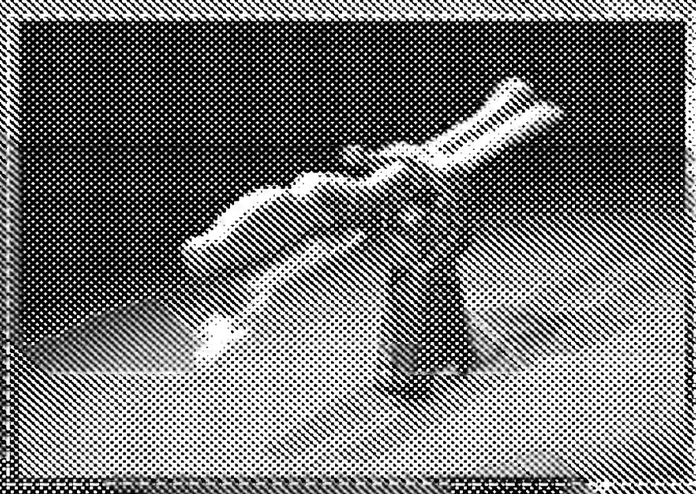
These benefits pave the way for the USET method to become the standard way of performing any intra-uterine procedure

USET's Device with Illumination System Option





USET's Device Assembly



Visit us at:
www.usetmedical.com

USET
Medical Ltd.

Annex 3

Lars Happel [l.happel@ivf-saar.de]
נשלח: יום שלישי 30 דצמבר 2008 15:32
אל: michal@devir.co.il
נושא: vaginal speculum with ultrasound facility

Hello,
We are very interested in your vaginal speculum with ultrasound facility for performing ultrasound guided embryo transfer.
Please send us prices and probes.
Thanks

Dr.med. Lars Happel
Facharzt für Frauenheilkunde und Geburtshilfe
gynaekologische Endokrinologie und Reproduktionsmedizin
GMP Thaele-Happel-Giebel-Nassar, IVF-Saar
Kaiserstrasse 7, 66111 Saarbruecken
Tel.: +49-681-93632-0
Fax.: +49-681-93632-10
E-Mail: zentrum@ivf-saar.de
Web: www.ivf-saar.de

Michael Berman [michael@sepalreprodevices.com]
נשלח: יום חמישי 24 אוגוסט 2006 23:42
אל: Michal@devir.co.il
עותק: ellen@sepalreprodevices.com; 'Jennifer Berman'
נושא: Suggested Agreement Structure

Dear Michal,

Below are some of my thoughts for how we can work together to promote continued development and marketing/sales of the USET Speculum.
I've structured this to "front load" payments to you so that you will be able to complete the development of the speculum; build and complete a steel mold; and have some money to continue working on other projects that your company may have in the pipeline. This structure will also allow Sepal the time to build the market demand and achieve a solid revenue stream resulting in a long term royalty for your company. I am proposing a royalty stream to last for as long as 20 years. We can discuss in further detail the potential size of the market and our projections so you can calculate the potential of the arrangement.

The principal elements of the arrangement would be:

- USET retains rights to Patent
- Sepal has exclusive world-wide rights to market and sell the device, together with any and all improvements
- Sepal will manage the FDA process and pay costs on behalf of USET in order to begin the application process as soon as letter of intent is signed
- Initial production of 10,000 units will come from USET (manufacturing), with a transfer price for these units TBD
- Sepal will contract directly with a manufacturer (likely in China) once steel molds are completed (w/assistance and interface of USET)
- USET will complete development of disposable device
- Sepal would pay a fee of $500,000 for the exclusive world wide rights to the speculum, and for ownership of the finished steel mold.
- Payments would be made in 3 installments:
    1. Upon signing of the agreement, Sepal will commit to pay $25,000 for the cost of the FDA consultant and process to gain approval. (USET will have a copy of the agreement that Sepal will enter into with MDC Associates to complete this work. This cost is estimated to be $25,000-$30,000.)

2. $250,000 paid upon FDA approval (expected 90-120 days from submittal).
3. $125,000 paid on the 1st anniversary of obtaining FDA approval.
4. $100,000 paid on the 2nd anniversary of obtaining FDA approval.
5. Payments made under paragraphs (1-4 above) would be credited towards the per-unit royalty fees due to USET.

- On going royalty for 10 years of $2.00 per unit.
- On-going royalty for years 11 through 20 (or shorter if the patent expires before then) of @$1.00 per unit
- USET grants Sepal a right of first refusal on similar terms, on all other devices developed by it.
- Credit terms on 1st 10,000 units tbd
- Liability insurance coverage tbd

If this works for you, we will immediately work on raising the funds to begin payments to you.
Please let me know your thoughts so we can continue our dialogue.
All the best,

Michael
Michael Berman
Chairman
Sepal Reproductive Devices, Inc

Michal Devir [michal@devir.co.il]
נשלח: יום חמישי 03 אוגוסט 2006 18:52
אל: 'IVP@a-teleport.com'
עותק: 'avraham@yozmot.org'; 'adrian@netvision.net.il'; Gershon G (gershon@rs.co.il)
נושא: RE: Taras Argat

Dear Sir,

Thanks for your inquiry. The answers to your questions are below (in blue). please do not hesitate to contact us again with any further questions.

best regards

Michal Devir, MD
Director
USET Medical Ltd
Hamachleva 117 Kfar Vitkin, Israel 40200
Tel: + 972-9-8663087
Fax: + 972-9-8664686
Cell: + 972-54-4773736
e-mail: michal@usetmedical.com
michal@devir.co.il
www.usetmedical.com

From: ????? ????????? [mailto:IVP@a-teleport.com]
Sent: Thursday, August 03, 2006 6:06 AM
To: dror@usetmedical.com
Subject: Taras Argat

Dear Sirs,

Our clinic would like to buy a speculum with vaginal sensor. We require the following information:
1) Can you provide video presentation how it works in practice with a patient. YES. YOU CAN ALSO HAVE A LOOK AT OUR WEB-SITE ON HOME PAGE and IN THE PRODUCT PAGE -A LINK AT THE LEFT SIDE
2) Do diameter and weight of ultrasound diagnostic sensor play an important role? NO Does its cord hinder when you transfer embryos in IVF cycle? Is it comfortable for a doctor to make the procedure? NO PROBLEM AT ALL Do we need an Assistant to hold the sensor? NO - YOU DON"T NEED AN ASSISTANT, THIS IS A PART OF THE BENEFITS OF THE DEVICE What is the minimum length of catheter for embryo transfer? EVERY ONE WILL FIT, BUT 23 IS RECOMMENDED We need brief instruction how the sensor is used during the IVF procedure. HAVE A LOOK AT THE MOVIE IN THE WEB-SITE AND IF YOU HAVE FURTHER QUESTIONS WE CAN ARRANGE A CONFERENCE ALL WITH OUR MEDICAL DIRECTOR.
3) Is the speculum with vaginal sensor disposable or not? THE IDEA IS TO HAVE IT ALL

DISPOSABLE- HOWEVER THE BASIC PART COULD BE REUSABLE FOR ABOUT 10-15 PROCEDURES

4) Its price, where and how it can be bought. THE PRICE IS TO BE DETERMINED BY THE LOCAL DISTRIBUTOR. WE DON'T HAVE A DISTRIBUTOR YET IN UKRAINE. WE CAN MEANWHILE SELL LIMITED QUANTITIES TO USERS. PRICE IS DETERMINED BY QUANTITIES. HOW MANY WERE YOU THINKING OF?

Thank you for your anticipated cooperation,

Taras Argat
"Dnepr IVF"
Dnepropetrovsk
Ukraine
www.gyn.com.ua